

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20716

Trade Name: VICOPROFEN

**Generic Name: HYDROCODONE
BITARTRATE/IBUPROFEN**

Sponsor: KNOLL PHARMACEUTICAL CO.

Approval Date: SEPTEMBER 23, 1997

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APPLICATION: NDA 20716

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
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Application Number: NDA 20716

APPROVAL LETTER



Food and Drug Administration
Rockville MD 20857

NDA 20-716

Knoll Pharmaceutical Company
Attention: Robert Ashworth, Ph.D.
Director, Regulatory Affairs
199 Cherry Hill Road
Parsippany, New Jersey 07054

SEP 23 1997

Dear Dr. Ashworth:

Please refer to your new drug application dated April 25, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vicoprofen (hydrocodone bitartrate/ibuprofen tablets). Please refer to our approvable letter dated April 17, 1997.

We acknowledge receipt of your amendments and submissions dated May 23, June 19, July 14 and 16, and August 14, 19, 22, and September 5, 1997.

This new drug application provides for treatment of short-term (generally less than 10 days) management of acute pain.

We have completed the review of this application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the September 5, 1997, draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the September 5, 1997, draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

However, you may continue to use the existing stock of the current package insert and carton label as submitted on August 19 and 22, 1997, for up to 90 days after the date of this letter.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-716. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

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We remind you of the Phase 4 commitments specified in your submission dated June 19, 1997.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of the studies. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Victoria Lutwak, Project Manager, at (301) 827-2090.

Sincerely,

M. Weintraub 9/23/97

Michael Weintraub, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research